The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte William D. Griffith

Application No. 10/000,311

ON BRIEF

MAR 3 1 2005

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Before SCHEINER, ADAMS and GREEN, <u>Administrative Patent Judges</u>.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 6, 12-19, 21, 24, 26-28 and 30-31. The examiner has indicated that claims 1-5, 7 and 9-11 are allowable. Page 3, Final Rejection, mailed July 1, 2003. Claims 20, 22, 23, 25, 29 and 32 are cancelled. The only remaining pending claim is claim 8. While appellant recognizes (Brief,

¹ This appeal is substantially similar to Appeal No. 2004-1503, Application No. 09/606,808; Appeal No. 2004-1506; Application No. 09/788,334; Appeal No. 2004-2317, Application No. 09/771,938; Appeal No. 2004-2343, Application No. 09/772,520; and Appeal No. 2005-0396, Application No. 10/077,589, which all share the same assignee, Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation. Accordingly we have considered these appeals together.

page 2) that claim 8 was rejected in the Final Office Action², appellant does not include claim 8 as part of the subject matter of the instant appeal. <u>Id.</u>, <u>see also</u>, appellant's statement of the Issues on Appeal (Brief, page 3), which does not include claim 8. In this regard, we note, appellant's statement (Brief, page 19), "[t]he rejection of claim 8 concerns a minor clerical error easily corrected by amendment and thus has not been appealed. The examiner also recognized (Answer, bridging sentence, pages 2-3), "the indefiniteness rejection of claim 8 is not being contested…." Since appellant has conceded to the examiner's rejection of claim 8 and has not placed claim 8 before us on appeal, we have not considered claim 8 in our deliberations.

Claims 6, 12, 17, 19, 26 and 30 are illustrative of the subject matter on appeal and are reproduced below. In addition, for convenience, we have reproduced allowable claims 1, 2, and 11 below:

- 1. Seed of corn inbred line designated LH321, representative seed of said line having been deposited under ATCC Accession No. _____.
- 2. A corn plant, or parts thereof, produced by growing the seed of claim 1.
- 6. The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility.
- 11. A method for producing a hybrid corn seed comprising crossing a first inbred parent corn plant with a second inbred parent corn plant and harvesting the resultant hybrid corn seed, wherein said first inbred parent corn plant or second said parent corn plant is the corn plant of claim 2.

² According to the examiner (page 3, Final Rejection, mailed July 1, 2003), claim 8 remains "rejected under 35 U.S.C. [§] 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated on pages 10-11 of the last Office [A]ction." At page 10 of this "last" Office Action, mailed January 13, 2003, the examiner finds "[c]laim 8 is indefinite in its recitation in line 1 of 'the...protoplasts' which lacks antecedent basis in claim 6. Amendment of claim 8, line 1 to delete 'the' before 'cells' would obviate this rejection."

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- 12. A hybrid corn seed produced by the method of claim 11.
- 17. A method for producing inbred LH321 seed, representative seed of which have been deposited under ATCC Accession No. _____, comprising:
 - a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH321, said collection also comprising seed of said inbred;
 - b) growing plants from said collection of seed;
 - c) identifying inbred parent plants;
 - d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
 - e) harvesting the resultant seed.
- 19. A method for producing a LH321-derived corn plant, comprising:
 - a) Crossing inbred corn line LH321, representative seed of said line having been deposited under ATCC [A]ccession [N]umber ______, with a second corn plant to yield progeny corn seed; and
 - b) Growing said progeny corn seed, under plant growth conditions, to yield said LH321-derived corn plant.
- 26. The corn plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.
- 30. A method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.

The references relied upon by the examiner are:

Hunsperger et al. (Hunsperger)

5,523,520

Jun. 4, 1996

Eshed et al. (Eshed), "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato," Genetics, Vol. 143, pp. 1807-17 (1996)

Kraft et al. (Kraft), "Linkage Disequilibrium and Fingerprinting in Sugar Beet," Theoretical and Applied Genetics, Vol. 101, pp. 323-36 (2000)

GROUNDS OF REJECTION

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "further defined as comprising a gene conferring male sterility."

Claims 26-28 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "transformed so that its genetic material contains one or more transgenes."

Claims 6, 12-19, 21, 24, 26-28, 30, and 31 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 6, 12-19, 21, 24, 26-28, 30 and 31 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

BACKGROUND

According to paragraph 23 of appellant's specification, the present invention

relates to the seeds of inbred corn line LH321, to the plants [and plant parts] of inbred corn line LH321 and to methods for producing a corn plant produced by crossing the inbred line LH321 with itself or another corn line, and to methods for producing a corn plant containing in its genetic material one or more transgenes and to the transgenic corn plants produced by that method.

Paragraphs 44-55 of appellant's specification disclose morphologic and "other" characteristics of the inbred corn line LH321. On this record the examiner has indicated that claims drawn to plants, plant parts, and seed of the corn variety designated LH321 are allowable. See e.g., claims 1-5, 7, and 10, and page 3 of

the Final Rejection, mailed July 1, 2003, wherein the examiner states "[c]laims 1-5, 7 and ... [10] are allowed."

A second aspect of the present invention comprises "hybrid corn seeds and plants produced by crossing the inbred line LH321 with another corn line." Specification, paragraph 23, see also claims 12-16. On this record the examiner has indicated that claims drawn to a process of producing corn seed wherein the process comprises crossing a first parent corn plant with a second parent corn plant are allowable. See e.g., claim 11, and Final Rejection, mailed July 1, 2003, wherein the examiner states claim 11 is allowed.

A third aspect of the present invention is a corn plant from the inbred corn line LH321 further comprising "a cytoplasmic factor that is capable of conferring male sterility" (specification, paragraph 24); or transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements" (see e.g., claims 26-28). As appellant explains (specification, paragraph 13), "[I]t should be understood that the inbred can, through routine manipulation of cytoplasmic or other factors, be produced in a male-sterile form." According to appellant (specification, paragraph 67)

scientists in the filed of plant biology developed a strong interest in engineering the genome of plants to confer and express foreign genes, or additional, or modified versions of native, or endogenous, genes (perhaps driven by different promoters) in order to alter the traits of a plant in a specific manner. Such foreign additional and/or modified genes are referred to herein collectively as "transgenes". Over the last fifteen to twenty years several methods for producing transgenic plants have been developed, and the present invention, in particular embodiments, also relates to transformed versions of the claimed inbred line.

A final aspect of the present invention is directed to a process of producing an inbred corn plant <u>derived</u> from a plant of the inbred corn line LH321 (<u>see e.g.</u>, claims 11, 19 and 30), as well as hybrid plants and seed resulting from such a process (<u>see e.g.</u>, claims 12-16). As discussed, <u>supra</u>, the examiner has indicated that claim 11 was allowable. According to appellant's specification (paragraph 56),

[t]his invention is also directed to methods for producing a corn plant by crossing a first parent corn plant with a second parent corn plant, wherein the first or second corn plant is the inbred corn plant from the line LH321. Further, both first and second parent corn plants may be from the inbred line LH321. Therefore, any methods using the inbred corn line LH321 are part of this invention: selfing, backcrosses, hybrid breeding, and crosses to populations. Any plants produced using inbred corn line LH321 as a parent are within the scope of this invention.

Against this backdrop, we now consider the rejections of record.

DISCUSSION

Definiteness:

Claims 6 and 26-28 stand rejected under 35 U.S.C. § 112, second paragraph. For the following reasons we reverse.

Claim 6

According to the examiner (Answer, page 3), "the recitation 'further defined as comprising a gene conferring male sterility' ... appears to broaden the scope of its parent claim, or to raise some doubt as to whether the corn plant of claim 6 must be male sterile." In this regard, the examiner finds (id.), "[t]he specification does not define plants expressing all the physiological and morphological characteristics of LH321 as being male sterile, or as comprising a

gene that confers male sterility; in fact, the plant of claim 2 (from which claim 6 depends) is male fertile."

Initially, we note that claim 6 does not require that the corn plant express all the physiological and morphological characteristics of LH321. To the contrary, this appears to be the subject matter of claim 5, which the examiner has indicated to be allowable. Page 3, Final Rejection, mailed July 1, 2003. As we understand claim it, claim 6 is drawn to a corn plant, or parts thereof, produced by growing the seed of claim 1, wherein the plant or plant parts further comprise a gene conferring male sterility. In our opinion, claim 6 further limits the subject matter of claim 2, by requiring the plant of claim 2 to further comprise a gene conferring male sterility. Accordingly, we disagree with the examiner that claim 6 fails to further limit the subject matter of claim 2, from which it depends.

In addition, we fail to understand the examiner's statement that "claim 6 does not incorporate all elements of the parent claim [(claim 2)]." As discussed above, claim 6 depends from claim 2, thus all the elements of claim 2 are present in claim 6. Claim 6, however, possesses an additional limitation not found in claim 2 – a gene conferring male sterility. Thus, the male fertile plant of claim 2, is now male sterile as a result of the additional limitation added in claim 6. The examiner provides no evidence that male fertile plants cannot be made male sterile. To the contrary, we recognize the examiner's suggestion that appellant add two new claims drawn to (1) "[a] method of producing a male sterile corn plant comprising transforming the plant of claim 2 with nucleic acid

molecule that confers male sterility; and (2) "[a] male sterile corn plant produced by the ..." suggested method claim above.

Notwithstanding the examiner's assertion to the contrary, in our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). Accordingly, we reverse the rejection of claim 6 under 35 U.S.C. § 112, second paragraph.

Claims 26-28

According to the examiner (Answer, page 4), the recitation in claim 26 that the claimed corn plant be "transformed so that its genetic material contains one or more transgenes' ... appears to broaden the scope of claim 2, or raises some doubt as to whether the plant has all of the traits expressed by the plant of claim 2." According to the examiner (id.), "[s]ince claim 2 is drawn to a plant with defined characteristics and genotypes which exclude the presence of introduced transgenes, it is confusing to characterize these plants as comprising additional genes." In addition, the examiner finds (id.), "[d]ependent claims 27-28 fail to remedy the deficiency of claim 26.

As with the discussion of claim 6 above, claim 26 simply adds a further limitation to claim 2. Specifically, that the plant or plant parts of claim 2 "have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements." Accordingly, notwithstanding the examiner's assertion to the contrary, in our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v.

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Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). Accordingly, we reverse the rejection of claims 26-28 under 35 U.S.C. § 112, second paragraph.

Written Description:

Claims 6, 12-19, 21, 24, 26-28, 30 and 31 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 12-16

According to the examiner (Answer, page 7),

A review of the language of claims 12-16 indicates that the claims are drawn to a genus, i.e., any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant LH321 with any second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-LH321 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-LH321 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

Accordingly the examiner finds (Answer, page 13),

[g]iven the lack of written description in the specification regarding any of a multitude of non-LH321 parents to be used in a backcrossing breeding method or any other classical breeding method, one skilled in the art would not have recognized Appellant to have been in possession of the claimed hybrids or progeny plants as recited in claims ... 12-16.

As we understand it, the examiner's concern (see e.g., Answer, pages 15-16) is that since the hybrids inherit only ½ of their diploid³ set of chromosomes from the plant of corn variety LH321, a person of skill in the art would not have viewed the teachings of the specification as sufficient to demonstrate that appellant was in possession of the genus of hybrid seeds and plants encompassed by claims 12-16. According to the examiner (Answer, page 16), "[t]hat all hybrids will inherit half of their alleles from LH321 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids."

There is no doubt that the expressed gene products of a hybrid plant, e.g., the morphological and physiological traits, of LH321 and a non-LH321 corn plant will depend on the combination of the genetic material inherited from both parents. See Answer, page 22. Nevertheless, we disagree with the examiner's conclusion (id.) "[t]hat all hybrids will inherit half of their alleles from LH321 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids."

On these facts, we find it necessary to take a step back and consider what is claimed. As we understand the them, the claims are drawn to a F₁⁴ hybrid seed (claims 12, 14 and 15) or plant/plant part (claim 13, and 16) resulting from a

³ According to appellant's specification (page 21), "[i]n a diploid cell or organism, the two alleles of a given gene occupy corresponding loci on a pair of homologous chromosomes." Stated differently, diploid means a cell or organism having two sets of chromosomes.

⁴ According to appellant's specification (page 3), "[a] single-cross hybrid is produced when two inbred lines are crossed to produce the F₁ progeny."

cross between the inbred corn plant LH321 and a non-LH321 corn plant. The claims do not require the hybrid to express any particular morphological or physiological characteristic. Nor do the claims require that a particular non-LH321 corn variety be used.⁵ All that is required by the claims is that the F₁ hybrid has one parent that is a plant of corn variety LH321. Since the examiner has indicated that the seed and the plant of the inbred line LH321 are allowable (see claims 1 and 2), there can be no doubt that the specification provides an adequate written description of this inbred corn line. In addition, the examiner recognizes (Answer, page 7) that appellant's specification describes four exemplary hybrids wherein one parent was a plant of the inbred corn line LH321, see e.g., specification, pages 31-33. Accordingly, it is unclear to this merits panel what additional description is necessary.

As set forth above, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Reiffin. Here the F₁ hybrid seed or plant has one parent that is a plant of the inbred line LH321. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For the foregoing

⁵ According to appellant (Brief, page 16), "hundreds or even thousands of other maize plants ... were known at the time the application was filed...."

reasons it is our opinion that appellant has provided an adequate written description of the subject matter set forth in claims 12-16. Accordingly, we reverse the rejection of claims 12-16 under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 17-19, 21, 24, 30 and 316

According to the examiner (Answer, page 12), "[c]laims 19, 21, 24, 30 and 31 read on processes involving the repeated outcrossing of the exemplified inbred to multitude of genetically unrelated and uncharacterized corn plants for multiple generations." As the examiner explains (id.), "LH321 may be used only in the initial cross, and then the progeny of this cross may be crossed to a multitude of unrelated and uncharacterized corn plants for up to 7 times (as recited in claim 21) or ad infinitum (as claimed in claims 19, 24, 30 and 31)." In this regard, the examiner finds (id.),

[t]he specification fails to disclose or describe any progeny resulting from such crosses, wherein said progeny could contain only a small portion of the LH321 genome, if any at all, and wherein said progeny would contain a majority of undisclosed and uncharacterized genetic material from a multitude of undisclosed and uncharacterized parents. Furthermore, no description has been provided for the progeny of such crosses with regard to even one morphological trait of said progeny containing a majority of non-LH321 genetic material.

Thus, the examiner concludes (Answer, page 13), "given the lack of an adequate written description of the claimed progeny plants, any method of using said

⁶ We note that while the examiner includes (Answer, page 13) claims 17 and 18 with claims 19, 21, 24, 30 and 31 in concluding that the claims are inadequately described, the examiner has explained (Answer, pages 12-13) the basis of this rejection as it applies to claims 19, 21, 24, 30 and 31.

progeny plants in further crosses, as claimed in claims 17-19, 21, 24, 30 and 31, would also be inadequately described.

As we understand the examiner's argument, not only does appellant have to provide a written description of the starting corn plant (LH321), but appellant also must look into the future to determine every other potential corn plant that someone may wish to cross with the LH321 inbred line, and provide written descriptive support for not only every other corn plant that could be crossed with this line, but also the resulting progeny of each cross.

As set forth in Reiffin, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the method of producing an inbred corn plant requires a plant of the inbred corn line LH321 be used as the starting material. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filling date sought, he or she was in possession of the invention" [emphasis added].

Vas-Cath. The examiner has indicated that a claim to the plant of the inbred corn line LH321 is allowable, see e.g., appellant's claim 2. Therefore, in our opinion, there can be no doubt that appellant was in possession of this plant, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in claims 17-19, 21, 24, 30 and 31.

In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between the LH321 inbred line and some other corn plant

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represents. The inventions of claims 17-19, 21, 24, 30 and 31 are drawn to the use of the LH321 inbred line as the starting material, to produce an inbred corn plant. In this regard, we emphasize, the claims are <u>not</u> drawn to a seed or plant that is the result of such a cross. Therefore, we are not persuaded by the examiner's assertion (Answer, page 11),

[t]he product of the method of claim 31, ... would contain substantial amounts of non-LH321 genetic material [that] has not been characterized or described, because the collection of traits that it possesses has not been disclosed, and because it contains substantial amounts of non-LH321 genetic material which itself has not been described.

Accordingly, for the foregoing reasons, it is our opinion that appellant has "convey[ed] with reasonable clarity to those skilled in the art that, as of the filing date sought, [they were] in possession of the invention," <u>Vas-Cath</u> (emphasis omitted). Therefore, we reverse the rejection of claims 17-19, 21, 24, 30 and 31 under the written description provision of 35 U.S.C. [§] 112, first paragraph.

Claims 6 and 26-28

According to the examiner (Answer, page 13), "[c]laims 26-28 are drawn towards L321 plants further comprising a foreign gene ('transgene') which was previously isolated as a piece of DNA, and then stably inserted into the corn genome by transformation." The examiner finds, however, that "the specification does not describe identified or isolated single loci for all corn plant traits."

Answer, page 14. More specifically, the examiner finds (id.), claims 26-28

⁷ <u>See</u> Answer, page 12, wherein the examiner also recognizes that "LH321 may be used only in the initial cross...."

"broadly encompass single loci that have not been discovered or isolated." To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath.

Nevertheless, it may be that the examiner's concern (Answer, page 22), is that "isolated single genes or loci that confer yield enhancement or yield stability ... have not been discovered or isolated...." In this regard, we note the examiner's assertion (id.), "[a]ppellant cannot be in possession of LH321 plants transformed with gene(s) conferring these traits." The examiner, however, provides no evidence to support the assertion that a person of ordinary skill in the art would not recognize that single loci for yield enhancement or yield stability are known in the art. In this regard, we note that appellant discloses (specification, paragraph 133), "[m]any single locus traits have been identified ... examples of these traits include, but are not limited to, ... enhanced nutritional quality, industrial usage, yield stability, and yield enhancement." It appears that the examiner has overlooked appellant's assertion that single locus traits for yield stability and yield enhancement are well known in the art. To this end, we direct the examiner's attention to, for example, United States Patent No.

5,936,145 ('145)⁸, issued August 10, 1999, which is prior to the filing date of the instant application. For clarity, we reproduce claims 8, 29 and 39 of the '145 patent below:

- 8. A corn plant having all the physiological and morphological characteristics of corn plant 87DIA4, a sample of the seed of said corn plant having been deposited under ATCC Accession No. 203192.
- 29. The corn plant of claim 8, further comprising a single gene conversion.
- 39. The single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability.

As we understand it, claim 39 of the '145 patent, is drawn to a corn plant which comprises a single gene conversion, wherein the gene confers enhanced yield stability. Thus, contrary to the examiner's assertion it appears, for example, that a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. We remind the examiner "a patent need not teach, and preferably omits, what is well known in the art." Hybritech Incorporated v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

We remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the

⁸ We note that the assignee of the '145 patent is DeKalb Genetics Corporation. The assignee of the present application is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation.

examiner to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description.

Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that single loci that govern, for example, yield enhancement or enhanced yield stability are not described.

Furthermore, we recognize the examiner's assertion (Answer, page 13) that "one skilled in the art would not have recognized [a]ppellant to have been in possession of the claimed hybrids or progeny plants as recited in claim[] 6...." As we understand it, claim 6 is drawn to a corn plant produced by growing the seed of corn inbred line LH321 further defined as comprising a gene conferring male sterility. The examiner has provided no evidence on this record as to why such a corn plant is not adequately described in appellant's specification. In this regard, we note that in the rejection under 35 U.S.C. § 112, second paragraph, the examiner suggested adding two new claims directed at (1) a method of producing a male sterile corn plant comprising transforming the plant of claim 2 with a nucleic acid molecule that confers male sterility, and (2) a male sterile corn plant produced by the method set forth above. Accordingly, we are not persuaded by the examiner's assertion that the specification does not provide an adequate written description of claim 6.

Further, we direct the examiner's attention to claim 16 of related Appeal Nos. 2005-1506 and 2004-2317, which differ from claim 6 on this record only in the variety of corn. In addition, we note that the disclosure of Appeal Nos. 2005-1506 and 2004-2317 and the instant application are substantially similar. However, in both Appeal Nos. 2005-1506 and 2004-2317 the examiner apparently found that appellant's specification provided an adequate written description of claim 16 as no rejection of this claim was made under the written description provision of 35 U.S.C. § 112, first paragraph. Accordingly, we find that the examiner has treated claim 6 in a manner that is inconsistent with the prosecution of similar claims in related applications 09/788,334 and 09/771938, which is the subject matter of Appeal Nos. 2004-1506 and 2004-2317 respectively.

For the foregoing reasons, we are not persuaded by the examiner's arguments. Accordingly, we reverse the rejection of claims 6 and 26-28 under the written description provision of 35 U.S.C. [§] 112, first paragraph.

Summary

For the foregoing reasons, we reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the written description provision of 35 U.S.C. § 112, first paragraph.

Enablement:

Claims 6, 12-19, 21, 24, 26-28, 30 and 31 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. The examiner finds

(Answer, page 39), claims 27-30 "are broadly drawn towards inbred corn plant l015011 further defined as having a genome comprising any single locus conversion, encoding any trait; or wherein the single locus was stably inserted into a corn genome by transformation." The examiner presents several lines of argument under this heading. We take each in turn.

I. Retaining the morphological fidelity of the original inbred line:

According to the examiner (Answer, page 30, emphasis added), "[I]t is not clear that single loci may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety...." With reference to Hunsperger, Kraft, and Eshed the examiner asserts (Answer, page 38), "[t]he rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome."

We note, however, that claims 26-28 (those which are drawn to a plant transformed with one or more transgenes) do not require that the plant <u>maintain</u> the genetic and morphological fidelity of the original inbred variety. Nor do claims 26-28 require that the resultant plant retain all of the "original plant's <u>genome</u>" as a result of a backcrossing technique. As appellant explains (specification, paragraph 41, emphasis added),

[s]ingle locus converted or conversion plant refers to plants which are developed by a plant breeding technique called backcrossing wherein <u>essentially all</u> of the desired morphological and physiological characteristics of an inbred are recovered in addition

to the single locus transferred into the inbred via the backcrossing technique or via genetic engineering.

We find nothing in the appellant's specification to indicate that the single locus converted plant retains <u>all</u> of the morphological and physiological traits, or <u>all</u> of the genome, of the parent plant in addition to the single locus transferred <u>via</u> the backcrossing technique. Accordingly, we disagree with the examiner's assertions to the contrary.

Further, while the examiner does not explain the basis for the rejection of claim 6 under this heading, we note as discussed supra, claim 6 is drawn to a corn plant produced by growing the seed of corn inbred line LH321 further defined as comprising a gene conferring male sterility. In this regard, we note that appellant's specification discloses (paragraph 19), "several methods of conferring genetic male sterility [that are] available [in the art]." We find no evidence in the Answer to suggest this disclosure in appellant's specification is incorrect, or insufficient. In addition, we note that the examiner's rejection of claim 6 is inconsistent with the manner in which a similar claim was treated in related applications 09/788,334 and 09/771,938, the subject matter of Appeal Nos. 2004-1506 and 2004-2317 respectively. Claim 16 of related applications 09/788.334 and 09/771,938, differs from claim 6 of the instant application only with regard to the corn variety. Nevertheless, while the disclosure in these related applications is substantially similar to the disclosure of the instant application, claim 16 was not rejected under the enablement provision of 35

U.S.C. § 112, first paragraph, in either of related applications 09/788,334 or 09/771,938.

Further, we recognize appellant's argument (Brief, page 16) that the examiner failed to establish a nexus between Hunsperger's discussion of petunias; Kraft's discussion of sugar beets; and Eshed's discussion of tomatoes, and the subject matter of the instant application - corn. Absent evidence to the contrary, we agree with appellant (id.), "the [examiner's] indication[9] that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support." That the examiner has failed to identify (Answer, page Answer, page 38) an example "in the prior art of plants in which linkage drag does not occur," does not mean that linkage drag is expected to occur in corn breeding, which according to appellant (Brief, page 16) "is extremely advanced and well known in the art." In this regard, we agree with appellant (Brief, pages 16-17), the examiner has improperly placed the burden on appellant to demonstrate that the examiner's unsupported assertion is not true. We remind the examiner, as set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

⁹ <u>See</u> Answer page 38, wherein the examiner asserts "[I]inkage drag appears to be a phenomenon that occurs in all plant types."

II. Corn molecular genetic markers:

According to the examiner (Answer, page 27),

[n]o guidance has been provided for the identification of any molecular genetic markers such as restriction fragment length polymorphisms [RFLPs] as claimed in claim 31, wherein said genetic molecular markers have been demonstrated to be inked to corn genes conferring agronomically desirable traits, or their use to breed and obtain improved corn genotypes using LH321 as the starting material.

Admittedly, we find the examiner's statement less than clear. However, as we understand it the examiner finds that the specification fails to enable claim 31 because a link between genes conferring agronomically desirable traits and RFLPs has not been established. However, as we understand claim it, claim 31 is drawn to a method of using a plant from the LH321 inbred corn line as the source of plant breeding material in the development of a corn plant in a corn plant breeding program using plant breeding techniques which are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, RFLP enhanced selection, genetic marker enhanced selection, and transformation. As appellant discloses (specification, paragraph 3), "[t]he complexity of inheritance influences choice of the breeding method." Appellant then provides a description of various breeding methods. See e.g., specification, paragraphs 3-13. In addition, appellant discloses (specification, ape 14), several reference books wherein "[d]escriptions of other breeding methods that are commonly used for different traits and crops can be found" In addition, appellant provides a description of various marker genes. See e.g., specification, paragraphs 69-75. Further, appellant discloses (specification,

paragraph 91), "[f]or the relatively small number of transgenic plants that show higher levels of expression, a genetic map can be generated, primarily via conventional FRLP, PCR and SSR analysis, which identifies the approximate chromosomal location of the integrated DNA molecule." In addition, appellant provides a reference "for exemplary methodologies in this regard..." Id. Faced with this disclosure, the examiner provides no evidence to support his assertion that appellant's specification does not provide an enabling disclosure of the invention set forth in claim 31.

As set forth in <u>In re Marzocchi</u>, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), the burden is on

the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

On this record, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In the absence of an evidentiary basis to support the rejection, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement. In this regard, we note that the burden of proof does not shift to appellant until

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the examiner first meets his burden. Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370.

Accordingly, we are not persuaded by the examiner's comments.

III. Non-exemplified breeding partners:

The examiner finds (Answer, page 27), "[n]o guidance has been provided regarding the morphological or genetic compositions of a multitude of non-exemplified breeding partners for crossing with LH321...." According to the examiner this is true whether a single cross is preformed to produce a hybrid corn plant as claimed in claims 12-16, or multiple crosses with non-LH321 parents over multiple generations as claimed in claims 19, 21, 24, 30 and 31, with or without multiple non-disclosed parents. ¹⁰

Claims 12-16:

As discussed <u>supra</u>, the examiner has interpreted these claims as directed to the product of a single cross of a LH321 plant and a non-LH321 plant.

<u>See</u> Answer, page 5, and 27. Accordingly, as we understand this record, claims 12-16 are drawn to F₁ hybrid seed, plant, or plant parts. The claims do not require the hybrid to express any particular morphological or physiological

¹⁰ We note that the examiner includes claim 14 in a discussion of "multiple crosses with non-LH321 parents over multiple generations." However, as we understand the claim, claim 14 is drawn to the seed produced by growing the corn plant of claim 13 and harvesting the resultant corn seed. Accordingly, it appears that the examiner has inadvertently included claim 14 together with claims 19, 21, 24, 30 and 31. As we understand claim 14, it should have been included with the rejection of claims 12, 13, 15 and 16. See e.g., Answer, page 5, wherein the examiner's treatment of claims 12-16 together as "drawn towards any hybrid corn seed produced by the process of crossing the inbred corn plant LH321 with any second, distinct, inbred corn plant; and any hybrid corn plant produced by growing said hybrid corn seed (claims 12-16). Accordingly, we have considered the examiner's argument regarding claim 14 together with claims 12, 13, 15 and 16.

characteristic. Nor do the claims require that a particular non-LH321 corn variety be used. All that is required by the claims is that the F₁ hybrid has one parent that is a plant of corn variety LH321.

Since the examiner has indicated that the seed and the plant of the inbred line LH321 are allowable (see claims 1 and 2), there can be no doubt that the specification provides an adequate written description of this inbred corn line. In addition, the examiner recognizes (Answer, page 7) that appellant's specification describes four exemplary hybrids wherein one parent was a plant of the inbred corn line LH321, see e.g., specification, pages 31-33. Accordingly, it is unclear to this merits panel what additional enabling description is necessary. In our opinion, appellant's specification provides an enabling description of F₁ hybrids wherein one parent is a corn plant of the LH321 inbred line.

Claims 17-19, 21, 24, 30 and 31:

We understand these claims to be drawn to methods of producing plants derived from LH321. Stated differently, the claims are drawn to methods of using LH321 inbred corn plants as the starting material to produce other inbred lines. In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between the LH321 inbred line and some other corn plant represents. The inventions of claims 17-19, 21, 24, 30 and 31 are drawn to the use of the LH321 inbred line as the starting material to produce an inbred corn plant. In this regard, we emphasize, these claims are not drawn to a seed or

¹¹ <u>See</u> Answer, page 12, wherein the examiner also recognizes that "LH321 may be used only in the initial cross...."

plant that is the result of such a cross. The examiner has provided no evidence on this record that person of ordinary skill in the art could not produce another inbred line, which uses a corn plant of the LH321 inbred line as the starting material. Therefore, we are not persuaded by the examiner's unsupported assertions to the contrary.

Accordingly, for the foregoing reasons, we reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the enablement provision of 35 U.S.C. § 112, first paragraph.

SUMMARY

We reverse the rejection of claims 6 and 26-28 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the enablement provision of 35 U.S.C. § 112, first paragraph.

We do not reach the merits of the rejection of claim 8 under 35 U.S.C. § 112, second paragraph, which was not presented for our review in this appeal.

REVERSED

Toni R. Scheiner

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

Lora M. Green

Administrative Patent Judge

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APPEALS AND

INTERFERENCES

Appeal No. 2004-1968 Application No. 10/000,311

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